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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,209	04/20/2006	Julie Hazel Campbell	4501-1016	9620

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,209	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 22, 2008 has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 13-16 are canceled. Claims 1-12, 17-24 are currently under examination.

Priority: The request for priority to NEW ZEALAND 521955, filed October 4, 2002, is acknowledged.

Objections and Rejections

Claims 17-20, 23 are objected to because of the following informalities:

Claims 17-20 recite the composition an aqueous solution, etc., and the composition a solid, etc., and the composition an aqueous solution, etc., respectively, and so forth. Claims 17-20 contain minor grammatical errors.

Claim 23, line 2 recites a product containing or processed from milk. The line does not make sense since it is unclear what the product is containing.

Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al. (WO 0100047; IDS). Elliott et al. disclose a method for reducing the incidence of cardiovascular disease and peripheral vascular disease comprising the steps of manufacturing and administering a dietary supplement in the form of a milk product including A^2 β-casein but substantially no A1 or B β-casein (p. 10-11 lines 307-311). Elliott et al. also disclose that both Type I and Type 2 diabetes increase the risk of coronary heart disease (p. 20 lines 577-578). In Experiment 1, Elliott et al. disclose the administration of Prosobee (soy preparation used as rat food) plus 10% type A^2 β-casein to study the incidence of diabetes (p. 13-14 lines 389-406; claims 1-11, 17-23). Elliott et al. disclose the β-casein A^2 can be obtained from *Bos indicus*, Icelandic dairy cows, goats (p. 23 lines 665-667; claim 12). Elliott et al. disclose food products made from type A^2 β-casein, including yogurt, cheese, dried milk powder, milk chocolate, wherein the β-casein A^2 can be fortified with additional compounds (p. 22 lines 637-655; claim 8). Elliott et al. do not explicitly teach the oral administration of β-casein A^2 to a mammal for reducing cholesterol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer the fortified β-casein A^2 supplement of Elliott et al. to a patient for reducing cardiovascular disease and associated conditions, such as high cholesterol because Elliott et al. disclose a fortified milk product comprising β-casein A^2 can be manufactured and

administered as a dietary supplement for reducing cardiovascular disease and peripheral vascular disease (claims 1-12, 17-24).

While Elliott et al. do not explicitly teach the elements of reducing cholesterol, apolipoprotein B, triglycerides, hypercholesterolemia, hyperlipidemia, atherosclerosis or that said β-casein is at least 95% β-casein A^2, these elements are believed to be unpatentable over Elliott et al. because Elliott et al. disclose the supplement comprises β-casein A^2 but substantially no A1 or B β-casein. Therefore, one of ordinary skill would recognize that the β-casein of Elliott et al. comprises solely of β-casein A^2 and at least 95% β-casein A^2. Regarding the elements of reducing cholesterol, apolipoprotein, triglycerides, hypercholesterolemia, hyperlipidemia, and atherosclerosis, one of ordinary skill would recognize that these are factors that are strongly correlated with an increased risk of heart disease, and are unpatentable over Elliott et al. because Elliott et al. disclose a method for reducing the incidence of cardiovascular disease by administering fortified β-casein A^2; and therefore, it would be reasonable to expect that said elements would be reduced upon administration of a fortified β-casein A^2 into a patient.

In their remarks, Applicants assert (1) the present invention is based on the first demonstration that administering β-casein A^2 has a positive therapeutic effect (i.e. lowers serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B, and/or triglycerides). However, Elliott et al. discloses a method for reducing Type I diabetes, cardiovascular disease, by providing a dietary supplement in the form of a milk product including β-casein A^2 fortified by addition of another compound (i.e., a tHcy-reducing agent). (2) The "principles" described by Elliott et al. on page 12 do nothing more than suggest that β-

casein A^1 or β-casein B is correlated with Type I diabetes, whereas β-casein A^2 is not. There is no statement of any positive effect of β-casein A^2 on diabetes, let alone on the serum levels of cholesterol and triglycerides. (3) Elliott et al. teach away from using β-casein A^2 to reduce serum levels of cholesterol and triglycerides. For example, Elliott et al. discuss that the reduction of vascular diseases is "directly through the use of tHcy-reducing agents" and "indirectly by reducing the incidence of diabetes through (a) provisional bovine milks high in the A2 variant of β-casein and low in A1 and B variants, and/or (b) exploitation of the immunological properties of β-casomorphin 9". (4) Referring to the Office action's comments about the disclosure on page 24 of Elliott et al., the Applicant notes that there is nothing in this disclosure that points the skilled person to a reduction in the serum levels of cholesterol and triglycerides. (5) Also, at page 3, the Office action fails to point out where in the single reference of Elliott et al. that a teaching or inference of reducing cholesterol, apolipoprotein, triglycerides, etc., resides. Applicant's arguments have been fully considered but they are not persuasive.

The instant claims are essentially drawn to a method of reducing serum levels of cholesterol and triglycerides in a mammal comprising orally administering to said mammal a composition comprising β-casein A^2.

(1a) Applicants are reminded that the use of open language "comprising" allows for anticipating by additional components. Therefore, the composition recited in claim 1 can comprise additional components in addition to β-casein A^2. Therefore, while the milk supplement of Elliott et al. may be fortified by a tHcy-reducing agent, said supplement still comprises β-casein A^2.

(2a) In the last paragraph on page 10 of Elliott et al. (cross-over to page 11), Elliott et al. disclose a broad aspect of their invention includes a method for reducing the incidence of cardiovascular disease comprising the steps of providing a dietary supplement in the form of a milk product including β-casein A^2 but no A1 or B β-casein and fortified by addition of a Group I compound (i.e. betaine, cobalamin, folic acid, pyridoxine (tHcy reducing agents); p. 1). Therefore, it would be reasonable for one of ordinary skill to interpret that Elliott et al. disclose a composition comprising β-casein A^2 has therapeutic value for reducing cardiovascular disease.

(3a) Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). In this instance, Elliott et al. disclose milk compositions comprising β-casein A^2 are intended to reduce cardiovascular disease directly through the use of tHcy reducing agents. However, Elliott et al. still discloses said compositions as a whole (i.e. to still include β-casein A^2). "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Elliott et al. do not explicitly disclose the role of β-casein A^2 in reducing cardiovascular disease; however, they do not discredit its role in the fortified milk composition and said milk compositions' intended use to reduce cardiovascular disease.

(4a) As was previously noted, it is well known in the art that factors associated with coronary heart disease include high levels of cholesterol, triglycerides, bad LDL, low levels of good HDL (MedlinePlus and emedicine reference pages; previously cited). Therefore, it would be reasonable for one of ordinary skill to recognize that if administering a fortified composition comprising β-casein A^2, it can reduce the incidence of coronary heart disease, then the risk factors associated with coronary heart disease would also be reduced, i.e. serum levels of cholesterol, LDL cholesterol, VLDL cholesterol, apolipoprotein B, and triglycerides.

(5a) See remarks under (4a).

At least for these reasons, the Elliott et al. reference is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

November 19, 2008